DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 5, 2014

STRECK INC
C/O MS. DEBORAH KIPP
REGULATORY AFFAIRS MANGER
7002 SOUTH 109TH STREET
OMAHA, NE 68128

Re: K141962
Trade/Device Name: XN CAL™
Regulation Number: 21 CFR 864.8150
Regulation Name: Calibrator for cell indices
Regulatory Class: Class II
Product Code: KRX
Dated: October 27, 2014
Received: October 28, 2014

Dear Ms. Kipp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

k141962

Device Name
XN CAL

Indications for Use *(Describe)*

XN CAL is used for the calibration and calibration verification of Sysmex XN series (XN-10, XN-11, XN-20, XN-21) analyzers. Assayed parameters include:

WBC (10^3/µL), RBC (10^6/µL), HGB (g/dL), HCT (%), PLT (10^3/ µL), and RET (%)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(k) Submitter: Streck
7002 South 109th Street
La Vista, NE 68128

Official Correspondent: Deborah Kipp, Regulatory Affairs Manager
Address: 7002 South 109th Street; La Vista, NE 68128
Phone: 402-537-5215
Fax: 402-537-5317

Date Prepared: April 18, 2014

Names

Trade Name: XN CAL™
Common Name: Assayed Hematology Calibrator
Classification Name: Calibrator for Cell Indices (864.8150)
Product Code: KRX
Panel: Hematology

Predicate Device:

XN CAL™ (K120745)

Intended Use:

XN CAL is used for the calibration and calibration verification of Sysmex XN series (XN-10, XN-11, XN-20, XN-21) analyzers. Assayed parameters include:

WBC (10^3/µL), RBC (10^6/µL), HGB (g/dL), HCT (%), PLT (10^3/ µL), and RET (%)

Description:

Per the FDA guidance document, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], a predicate device was selected in order to demonstrate substantial equivalence for XN CAL. The comparison to the predicate device is shown in the "Comparison to Predicate Device" section.

Comparison to Predicate Device

	XN CAL™ (K120745)-Predicate Device	**XN CAL™ -Candidate Device**	**Same or Differences**
Intended Use Statement	XN CAL is used for the calibration and calibration verification of Sysmex XN series (XN-10, XN-20) analyzers. Assayed parameters include: WBC (10^3/µL), RBC (10^6/µL), HGB (g/dL), HCT (%), PLT (10^3/ µL), and RET (%)	XN CAL is used for the calibration and calibration verification of Sysmex XN series (XN-10, XN-11, XN-20, XN-21) analyzers. Assayed parameters include: WBC (10^3/µL), RBC (10^6/µL), HGB (g/dL), HCT (%), PLT (10^3/ µL), and RET (%)	Addition of the XN-11 and XN-21 analyzers.
Open Vial Stability	4 hours	4 hours	Same
Closed Vial Stability	35 days	49 days	Extension of Closed Vial Stability Dating to 49 days
Reagents	XN CAL contains the following: stabilized red blood cell component(s), stabilized white blood cell component(s), stabilized platelet component(s), and stabilized nucleated red blood cell component(s) in a preservative medium.	XN CAL contains the following: stabilized red blood cell component(s), stabilized white blood cell component(s), stabilized platelet component(s), and stabilized nucleated red blood cell component(s) in a preservative medium.	Same
Storage Conditions	2 - 8˚C	2 - 8˚C	Same

Discussion of Tests and Test Results:

To substantiate the product performance claims for XN CAL, Streck collected product performance data for the following studies Open-Vial Stability, Closed-Vial Stability, and Precision Performance. The resultant data set established that XN CAL is safe and effective for its intended use and that the product is stable for the entire product dating. The product fulfills its intended use as instructed in the Instructions for Use.

Conclusions Drawn From Tests:

Study results show XN CAL to be consistently reproducible, substantially equivalent to the predicate products, and stable for the entire product dating. XN CAL is a safe and effective product, which fulfills its intended use when used as instructed in the Instructions for Use.